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Washington, DC 20307-5100

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Dear Sir:

This letter reports our preliminary findings on the determination of squalene in vials of an anthrax vaccine preparation.

Three vials of ANTHRAX VACCINE ADSORBED, Manufactured By MICHIGAN DEPARTMENT OF PUBLIC HEALTH, Lansing, Michigan, 48909, U.S. License No. 99, LOT FAV020, EXP 6 FEB 99, were received on 23 April 1999.

We have developed a sensitive, rapid assay method for squalene using high performance liquid chromatography. The assay specificity is based on chromatographic retention time and on the uv absorption characteristics of the analyte. The method sensitivity is ~0.7 nanogm squalene/10 microL injection, based on squalene in 2-propanol. The method linearity is 0.7 nanogm to 225 nanogm/10 microL injection with  $r^2 = .999$ , also based on squalene in 2-propanol. The method is currently undergoing validation.

We find no measurable amount of squalene in the vials. If any squalene were present, it would be less than 70 nanogm per 0.5 milliL vaccine preparation, which volume is the label dose.

We will prepare and submit our final report as soon as the study is completed.

Sincerely yours,

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